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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1601
Rockville, Maryland 20852

Reference: Docket No. 98D-1171: Draft "Guidance for Industry: For Platelet Testing and Evaluation of Platelet Substitute Products"

Sirs:

America's Blood Centers is pleased to submit comments on the draft Guidance for Industry for Platelet Testing and Evaluation of Platelet Substitute Products. In general, we find the guidance reasonable and appropriate.

Our only comment relates to the scope of the document. It is our understanding that the guidelines will be applied only to the development of new processes for platelet collection and new platelet products. We respectfully request that the final guidance include a specific statement explicitly excluding platelet collection procedures already performed or that will be performed in the future by blood centers using an FDA-approved method of collection and storage.

Yours truly,

Celso Bianco, M.D.

President

America's Blood Centers

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